IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

GRT-4062-143 In re Patent Application of Atty Dkt. C# M# AUG 2 0 2007 **PANDEY** C/A.U. 1625 Examiner: P.L. Morris Serial No. 10/520,166 Date: August 20, 2007 Filed: October 4, 2005 A NOVEL PROCESS TO PREPARE PIOGLITAZONE VIA SEVERAL NOVEL Title: **INTERMEDIATES** Commissioner for Patents P.O. Box 1450 Alexandria. NA 22313-1450 Sir: RESPONSE TO RESTRICTION REQUIREMENT This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon. Correspondence Address Indication Form Attached. Fees are attached as calculated below: minus highest number Total effective claims after amendment 22 x \$50.00 \$100.00 (1202)/\$50.00 (2202) \$ (at least 20) =previously paid for 20 minus highest number Independent claims after amendment 15 x \$200.00 \$0.00 (1201)/\$0.00 (2201) \$ previously paid for 15 (at least 3) =If proper multiple dependent claims now added for first time, (ignore improper); add \$360.00 (1203)/\$180.00 (2203) \$ Petition is hereby made to extend the current due date so as to cover the filing date of this One Month Extension \$120.00 (1251)/\$60.00 (2251) paper and attachment(s) Two Month Extensions \$450.00 (1252)/\$225.00 (2252) Three Month Extensions \$1020.00 (1253/\$510.00 (2253) Four Month Extensions \$1590.00 (1254/\$795.00 (2254) Five Month Extensions \$2160.00 (1255/\$1080.00 (2255) \$ \$130.00 (1814)/\$65.00 (2814) \$ Terminal disclaimer enclosed, add Applicant claims "small entity" status. □ Statement filed herewith 0.00 Rule 56 Information Disclosure Statement Filing Fee \$180.00 (1806) \$ 0.00 \$40.00 (8021) \$ Assignment Recording Fee \$ 0.00 Other: TOTAL FEE \$ 0.00 CREDIT CARD PAYMENT FORM ATTACHED. The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached. NIXON & VANDERHYE P.C. 901 North Glebe Road, 11th Floor By Atty: Gary R. Tanigawa, Reg. No. 43,180 Arlington, Virginia 22203-1808 Telephone: (703) 816-4000 Facsimile: (703) 816-4100 GRT:ap Signature:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

PANDEY et al.

Appln. No. 10/520,166

Filed: October 4, 2005

AUG 7. 0 2007 B

Confirmation No. 5619

Atty. Ref.: 4062-143

T.C. / Art Unit: 1625

Examiner: P.L. Morris

FOR: NOVEL PROCESS TO PREPARE PIOGLITAZONE VIA SEVERAL NOVEL

INTERMEDIATES

RESPONSE TO RESTRICTION REQUIREMENT

August 20, 2007

Mail Stop Amendment

Hon. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed July 20, 2007, Applicants elect Group I (claims 1-2 and 5) with traverse for examination on the merits. They reserve the right to prosecute nonelected subject matter in a further patent application.

Notwithstanding the above election, reconsideration of the restriction requirement is requested because examination of all pending claims would not constitute a serious burden. In particular, an international search report and an international preliminary examination report (IPER) were established for claims 1-22. Thus, their examination in the same application would not constitute a serious burden.

In the alternative, Applicants disagree with the allegation in the Action that the pending claims lack unity of invention, and therefore belong to different groups of inventions. Although they agree with the Examiner's conclusion that the inventions are separately patentable, Applicants' traversal is based on the pending claims being so linked as to form a single general inventive concept under PCT Rule 13.1: i.e., the preparation of pioglitazone directly from a compound of formula 13 or 14 (cf. claims 1 and 5). In the international phase and this national phase (see the pending Office Action), no evidence was presented that a compound of formula 13 or 14 was not inventive. In fact, the IPER

concluded that claims 1-18 and 20-22 were both novel and inventive. Thus, Applicants submit that claims 1-22 should be examined together in this application.

Secondly, even if the Examiner were to find that claims to only one product (i.e., a compound of formula 1 or 9 or 13 or 14), claims to processes making that product, and claims to processes using that product belong in the same application, Applicants submit that claims 1-17 and 20-22 should be restricted into only <u>four</u> separate applications: i.e., (i) claims of Groups I-II, IV-VIII and XV (in part) (i.e., a compound of formula 14 as the special technical feature); (ii) claims of Groups III, IX-XI and XV (in part) (i.e., a compound of formula 13 as the special technical feature); (iii) claims of Groups XII-XIII (i.e., a compound of formula 9 as the special technical feature); and (iv) claims 18-19 (i.e., the compound of formula 1 as the special technical feature). Thus, claims 3-4, 6-12 and 20-22 should not be withdrawn from consideration and they should be examined in this application.

Thirdly, claim 1 which was elected in Group I is a linking or generic claim for processes that require reduction of a compound of formula 14 to a compound of formula 1. Therefore, in accordance with M.P.E.P. § 809, all process claims that recite such reduction should be examined in this application. Thus, claims 3-4, 6 and 9-12 should not be withdrawn from consideration and they should be examined in this application.

It is also noted that claims 19 and 20 are not grouped correctly. In contradiction to the allegation in the Office Action that Group XV is directed to compositions and their multiple uses, there are no claims to uses (e.g., method of treatment) of the composition of claim 19 included in Group XV and not all uses of a compound of formula 13 or 14 (only their use in methods of treatment) are included in Group XV. Applicants submit that a composition of claim 20 should be included with claims directed to a compound of formula 13 or 14, and use in methods of treatment, in the same group of claims.

Finally, under the Commissioner's Notice of March 26, 1996 (1184 OG 86) implementing the Federal Circuit's decisions of *In re Ochiai*, 37 USPQ2d 1127 (1995) and *In re Brouwer*, 37 USPQ2d 1663 (1996), Applicants reserve their right to request rejoinder.

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Applicants earnestly solicit an early and favorable examination on the merits. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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